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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,318	02/18/2004	Daniel J. Conklin	961094.00030	9433
27114 7590 02/25/2008 QUARLES & BRADY LLP 411 E. WISCONSIN AVENUE, SUITE 2040 MILWAUKEE, WI 53202-4497				
EXAMINER KWON, BRIAN YONG S				
ART UNIT		PAPER NUMBER		
1614				
NOTIFICATION DATE		DELIVERY MODE		
02/25/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

pat-dept@quarles.com

### Office Action Summary

**Application No.**

10/781,318

**Applicant(s)**

CONKLIN, DANIEL J.

**Examiner**

Brian-Yong S. Kwon

**Art Unit**

1614

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3,5,9,11 and 56 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,5,9,11 and 56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Application***

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. Claims 2-3, 5-9, 11 and 56 are currently pending in the application. However, claims 6-8 have been withdrawn from further consideration by the examiner as being drawn to non-elected invention.
2. Acknowledgment is made of applicant's filing of an amendment on 10/26/07. By the amendment, claims 4, 10 and 12 have been cancelled; claims 2,5 and 9 have been amended; claims 56 has been newly added.
3. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

### ***Specification***

4. The specification (page 3, line 14 through page 5, line 17) is objected. Although Drawings filed 02/18/04 are present with Figures 1A-C, 3A-B, 4A-B and 5A-C respectively, there are no clear descriptions of corresponding Figures in the specification. For instance, "Figure 1" should be corrected as "Figures 1A-C" (page 3, line 14).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 2-3, 5, 9, 11 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conklin et al. (Poster Presentation at University of Wisconsin-Eau Claire Biology Department, 2001, cited in IDS filed 06/10/2004) or Conklin, D. J. (Seminar at University of Wisconsin-Eau Claire Biology Department, April 2002, cited in IDS filed 06/10/2004), and further in view of Goldstein et al. (US 7129035) and Vidrio et al. (The Journal of Pharmacology and Experimental Therapeutic, 2003, Vol. 37, No. 2, pp. 497-504).

Either of Concline et al. (Poster Presentation) or Conklin (Seminar Slide Presentation) discloses in vitro study involving exposure of isolated human blood vessels to an organ bath or a physiologically acceptable solution containing 1mM of methylamine, wherein methylamine results in relaxation of human blood vessels. However, the reference is silent about "a buffer having an osmolarity in the range of about 280 to about 350 milliosmolar that buffers the solution to maintain a pH in a range of about 7.0 to about 7.8" or "the concentration of the exogenous substrate is in the range of 0.1 to 10 millimolar".

Goldstein and Vidrio are being supplied as a supplemental reference to demonstrate the routine knowledge in determining appropriate buffering capacity and/or pH of organ or living tissues-preserving solution or an organ bath, for example Krebs-He (see page 498, column 2, "Experiments in Rat Aortic Rings"; and abstract; column 5, lines 38-52; column 6, lines 8-42; claims of USP'035).

With respect to the specific osmolarity, generally differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Thus, in absence of superior or unexpected results of the claimed range of osmolarity and/or pH, the examiner maintains that the cited references in combination make obvious the instant invention.

With respect to the intended use for human implantation, one having ordinary skill in the art would have made reasonable correlation between in vitro experiments based on the result of methylamine in vasodilating effects of isolated human blood vessels and a practical utility in currently available form for humans or animals. Thus, the references in combination make obvious the instant invention.

### Conclusion

6. No Claim is allowed.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Brian-Yong S Kwon/  
Primary Examiner, Art Unit 1614